K112177

OCT 24 2011

510(k) SUMMARY

Submitted By:

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Submission Contact:

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Date Prepared:

July 25, 2011

Device Trade Name:

Sofia™ Analyzer and Influenza A+B FIA

Common Name:

Influenza A+B immunological test system

Predicate Devices:

- 3M™ Rapid Detection Flu A+B Reader and Test
- QuickVue® Influenza A+B Test

Device Classification/Name:

21 CFR 866.3330 / Influenza virus serological reagents

These tests are used to aid in the diagnosis of influenza and provide epidemiological information on influenza (21 CFR 866.3330). The Food and Drug Administration has classified serological test systems for the detection of influenza virus as Class I.

Intended Use:

The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the

predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine". Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Physiologic Basis of the Test:

Influenza viruses are causative agents of highly contagious, acute, viral infections of the respiratory tract.

Influenza viruses are immunologically diverse, single-stranded RNA viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been associated with a large epidemic of human disease. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.

Every year in the United States, on average 5% to 20% of the population contract influenza; more than 200,000 people are hospitalized from influenza complications; and, about 36,000 people die from influenza-related causes. Some people, such as older people, young children, and people with certain health conditions, are at high risk for serious influenza complications.

Device Description:

The Sofia Influenza A+B FIA employs immunofluorescence technology that is used with the Sofia Analyzer to detect influenza virus nucleoproteins.

The Sofia Influenza A+B FIA is a lateral-flow immunoassay that uses monoclonal antibodies that are specific for influenza antigens and have no known cross-reactivity to normal flora or other known respiratory pathogens.

Nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens are used for this test. The patient specimen is placed in the Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After disruption, the specimen is dispensed into the cassette sample well. From the sample well, the specimen migrates through a test strip containing various unique chemical environments. If influenza viral antigen is present, they will be trapped in a specific location.

Note: Depending upon the user's choice, the cassette is either placed inside of the Sofia Analyzer for automatically timed development (Walk Away Mode) or placed on the counter or bench top for a manually timed development and then placed into the Sofia Analyzer to be scanned (Read Now Mode).

The Sofia Analyzer will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. The Sofia Analyzer will display the test results (Positive, Negative, or Invalid) on the screen. The results can also be automatically printed on an integrated printer if this option is selected.

Device Comparison:

Item	Proposed Device	Predicate Devices	
Features	**Sofia™ Analyzer and Influenza A+B FIA**	**3M™ Rapid Detection Flu A+B Reader and Test**	**QuickVue® Influenza A+B Test**
Intended Use	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by virus culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine". Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	The 3M™ Rapid Detection Flu A+B Test is a qualitative immunochromatographic assay used to identify the presence of Influenza A and Influenza B nucleoprotein antigens in nasal wash, nasal aspirate, nasopharyngeal aspirate, and nasopharyngeal swab specimens from symptomatic patients. It is an *in vitro* diagnostic assay that aids in the rapid differential diagnosis of influenza viral infections in symptomatic patients. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment of other management decision.	The QuickVue® Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

Item	Proposed Device	Predicate Devices	
Features	**Sofia™ Analyzer and Influenza A+B FIA**	**3M™ Rapid Detection Flu A+B Reader and Test**	**QuickVue® Influenza A+B Test**
Read Results	Read results on instrument screen or print with optional printer	Read results on instrument screen or print with optional printer	Visual read for presence or absence of control and test lines
Instrument	Sofia Analyzer	3M Rapid Detection Reader	None
Calibrator	Yes – Calibration Cassette and QC Card provided	Yes – Lot Card contains calibration and expiration information	Not Applicable
Specimen Types	nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash	nasopharyngeal swab, nasal wash, nasal aspirate, and nasopharyngeal aspirate	nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash
Read Result Time	15 Minutes	15 Minutes	10 Minutes
External Controls	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs	Test kit contains Positive and Negative Control swabs

Summary of Performance Data:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate devices. These studies included the following:

1. A multi-center field clinical study was undertaken to document the performance characteristics of the test. Sensitivity and specificity were calculated using nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens.
2. A reproducibility study was performed to demonstrate intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various influenza concentrations.
3. Analytical studies included Limit of Detection, analytical reactivity, cross reactivity, interfering substances, operating temperature, lab precision/repeatability, viral transport media, inter-analyzer reproducibility, calibration cycle, and various flex studies.

Conclusion:

These studies demonstrated the substantial equivalence of the Sofia Analyzer and Sofia Influenza A+B FIA to existing products already marketed. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Quidel Corporation
c/o John D. Tamerius, Ph.D.
Sr. Vice President, Clinical and Regulatory Affairs
10165 McKellar Court
San Diego, CA 92121

OCT 24 2011

Re: K112177
Trade/Device Name: Sofia™ Analyzer and Influenza A+B FIA
Regulation Number: 21 CFR§ 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX, KHO
Dated: September 21, 2011
Received: September 22, 2011

Dear Dr. Tamerius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k112177

Device Name: Sofia™ Analyzer and Influenza A+B FIA

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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